

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE: COLUMBIA UNIVERSITY
PATENT LITIGATION

MDL NO. 1592
CIVIL ACTION No. 03-CV-11329 (MLW)

JOINT REPORT PURSUANT TO THE COURT'S ORDER DATED MAY 27, 2004

The parties to the above-captioned multidistrict litigation respectfully submit the following report as ordered by the Court.

A. Pending Motions

The following motions are pending:

1. Joint Motion of plaintiffs Biogen and Genzyme for a Preliminary Injunction

This motion is fully briefed.

2. Columbia's Motion to Stay Litigation Pending Conclusion of Reexamination and Reissue Proceedings

This motion will be fully briefed before the June 22, 2004 Scheduling Conference.

3. Columbia's Emergency Motion to Seal Document and Restrict Access to Confidential Information

This motion will be fully briefed before the June 22, 2004 Scheduling Conference.

B. Common Issues

All of the cases in this multidistrict litigation involve challenges to the validity and enforceability of U.S. Patent No. 6,455,275 (“’275 patent”) and to Columbia’s assertion that the plaintiffs are obligated to pay royalties under their licenses on account of the ’275 patent. Thus, common issues include invalidity (obviousness-type double patenting and defects under 35 U.S.C. §§ 101, 102, 103, and 112) and unenforceability (prosecution laches, inequitable conduct, and patent misuse). Plaintiffs believe that all these issues are common, since if Columbia’s patent is declared invalid or unenforceable for a reason pleaded by any one plaintiff and not another, no plaintiff will have any obligation to pay royalties. Several complaints make contract claims based on certain standard terms in the license agreements or the terms of the grant of title to the invention to Columbia by the National Institutes of Health. These are also common issues. Finally, claim construction is a common issue to many of plaintiffs’ invalidity defenses, including obviousness-type double patenting, defects under 35 U.S.C. §§ 101, 102, 103, and 112, and inequitable conduct.

C. Issues Unique to Particular Cases

Amgen’s complaint includes a claim of non-infringement. Further, Columbia has indicated that it may bring infringement claims against other plaintiffs. Infringement claims, however, because they raise issues concerning the composition and manufacturing of each plaintiff’s particular products, raise issues unique to individual cases. Columbia believes, however, that plaintiffs in many cases use similar methods of manufacturing, making a portion of the technical issues relating to infringement common as well. Plaintiffs strenuously oppose this characterization of infringement issues, and believe that it is inappropriate for Columbia to speculate about plaintiffs’ various manufacturing processes. Moreover, these processes are

plaintiffs' jealously guarded trade secrets, and characterizing them as common issues invites disputes about the confidentiality of materials relating to them.

There are also unique issues concerning nonstandard clauses in the license agreements and the royalty payment histories of particular plaintiffs.

D. Implications of Pending Reexamination

The implications of the pending reexamination of the '275 patent will be discussed in the parties' briefing on Columbia's motion to stay this litigation for the duration of the reexamination proceeding. This motion will be fully briefed before the June 22, 2004 scheduling conference.

E. Proposed Pretrial Schedule

The parties' proposals for the pretrial schedule are set forth at Tab 1. While the parties have reached agreement on numerous issues, as reflected in the document at Tab 1, the parties are in disagreement as to the basic structure of certain aspects of the pretrial schedule and have set forth the reasons for their respective proposals on these aspects of the schedule below.

1. Plaintiffs' Position on Pretrial Schedule

Plaintiffs propose that the Court address common issues first. As set forth in the discovery schedule appended at Tab 1, plaintiffs believe that discovery and dispositive motion practice in these cases should be staged so that the common issues can be addressed before individual issues are considered. Plaintiffs seek this schedule because they are confident that Columbia's patent is invalid and unenforceable and that the case can be disposed of in its entirety on summary judgment. In addition, the case was referred to this Court as multidistrict litigation to address common, rather than individual, issues. Accordingly, plaintiffs believe that staging is

appropriate and will greatly enhance the efficiency with which the disputes between Columbia and plaintiffs are resolved.

Staging the litigation as suggested by plaintiffs will enable other matters to be addressed more efficiently in the unlikely event that the patent survives summary judgment. Discovery concerning the individual issues is likely to raise a host of problems arising from the fact that the various plaintiffs compete with each other and thus need to request substantial restrictions on the dissemination of their competitively sensitive documents and information. If the proceedings are staged, it will avoid the need to address these competitive concerns initially, thus streamlining the production of documents and information and minimizing sealed filings and discovery disputes concerning confidentiality. If the case ends with the first stage, as plaintiffs believe it will, the confidentiality problems raised by the issues unique to each case can be avoided entirely.

Plaintiffs request that expert disclosure and discovery precede claim construction. In this respect, plaintiffs' proposed schedule is typical for cases in this district and is particularly appropriate for this case. The alternative, proposed by Columbia, is for claim construction to be addressed early, before expert disclosures and discovery. Plaintiffs consider this schedule, which tracks the usual procedure in the Northern District of California, to be inappropriate for this case.

The parties are agreed that claim construction will be very important for the resolution of this case. For example, in its brief in support of its Motion for Stay, Columbia asserts, "The meaning of the claims in the '275 patent will be a fundamental issue in this case. Plaintiffs' double-patenting allegations turn on the interpretation of the patent claims." Given the acknowledged importance of claim construction in this case, plaintiffs believe that it is very important for both sides to gain a complete understanding of each other's respective contentions

concerning double-patenting through expert disclosures and discovery before engaging in the claim construction process. As it now stands, plaintiffs have no idea how Columbia proposes to distinguish the claims of the '275 patent from the virtually identical claims of its earlier patents (as it must to avoid a finding of obviousness-type double patenting). Columbia's proposal, to nail down claim construction early, appears to be tactical: it hopes to argue for particular claim interpretations without having to reveal how those constructions relate to its double-patenting arguments.

In essence, Columbia's proposal for early claim construction is an attempt to structure this proceeding according to the patent litigation rules of the Northern District of California, which advance claim construction to the beginning of the case. Plaintiffs, however, believe that these rules are inappropriate for this case. Indeed, in their opposition to Columbia's motion for multidistrict transfer to the Northern District of California, plaintiffs Biogen, Genzyme, Wyeth, and Abbott (along with now dismissed plaintiffs Serono and Baxter) argued that the Northern District of California was an inappropriate transferee district because its rules would put Columbia at an unfair tactical advantage for the reasons set forth above.¹

¹ In their brief suggesting that this Court was a more appropriate transferee court than the Northern District of California, plaintiffs Abbott, Baxter, Biogen, Genzyme, Serono, and Wyeth also argued as follows against the early claim construction rules of the Northern District of California:

Several commentators have pointed out the problems that may result from requiring judges to make claim construction rulings on an undeveloped record. *See, e.g.,* William F. Lee & Anita K. Krug, *Still Adjusting to Markman: A Prescription for the Timing of Claim Construction Hearings*, 13 Harv. J.L. & Tech. 55, 80 (1999); Edward V. Filardi & Douglas R. Nemec, *The Effect of Markman on Patent Litigation: Practical Considerations*, 714 Practicing L. Inst. 225 (2002), available on Westlaw at 714 PLI/Pat 225. Perhaps for this reason, most courts conduct *Markman* proceedings at a much later stage than does the Northern District. One survey found that approximately seventy percent of all claim construction proceedings were held after the close of discovery. *See American Bar Association Section of Intellectual Property Law 1999 Markman Survey*, Intell. Prop. L. Newsl. (A.B.A., Washington, D.C.), Spring 2000, at 12, 13, available on Westlaw at 18 No. 3 Intell. Prop. L. Newsl. 12. Notably, while district courts overall have had approximately a forty-two percent reversal rate in the Federal Circuit on claim construction, the reversal rate for the Northern District of California is more than fifty percent, suggesting, at a minimum, that early claim construction does not improve the quality of the result. Andrew T.

Plaintiffs request that briefing on dispositive motions occur concurrently with briefing on claim construction. Plaintiffs ask the Court to schedule the *Markman* and summary judgment briefing concurrently so that the claim construction positions of the parties will be presented in the context of the double-patenting disputes for which claim construction is likely to be important. Plaintiffs believe that the disputes about claim construction will be more intelligible if they occur against the backdrop of the double-patenting dispute instead of in a vacuum. Concurrent claim construction and summary judgment briefing may be unfair to a party accused of infringement, because such a procedure may focus a court's attention prematurely on the accused product, but in this case, where the principal common issues relate to validity and enforceability, handling those issues concurrently is the most appropriate procedure.

In addition to requiring the Court to tackle claim construction in a vacuum, Columbia's proposal has a further significant disadvantage: it is likely to inject a significant delay into the case schedule. Columbia has not proposed specific deadlines for summary judgment briefing, but it is reasonable to assume that Columbia seeks to conduct dispositive motion practice only after its proposed June 2005 expert disclosure deadline. Given the large amounts of money in controversy, and the fact that those amounts will be steadily increasing during the pendency of the case, plaintiffs respectfully request that the Court adopt a schedule that will permit a speedy resolution of the issues.

2. Columbia's Position on Pretrial Schedule

There are three major structural differences between the schedule proposed by plaintiffs and the schedule proposed by Columbia. Columbia believes that the structure that it has proposed for the schedule will lead to greater efficiency, conservation of resources, and

Zidel, Patent Claim Construction in the Trial Courts: A Study Showing the Need for Clear Guidance from the Federal Circuit, 33 Seton Hall L. Rev. 711, 747 (2003).

avoidance of duplicative proceedings, and is more in keeping with the goals of multidistrict litigation.

1. **Excluding Columbia's Claims from MDL Proceedings:** The first major structural difference is plaintiffs' proposal that this Court consider, and only allow discovery concerning, plaintiffs' allegations that the '275 patent is invalid and unenforceable, and defer any consideration of or discovery concerning Columbia's counterclaims claims against plaintiffs until after remand. Columbia believes that splitting this case into two phases—the first of which addresses only plaintiffs' claims and the second of which is fragmented among five different cases after remand—is unfair and inefficient.

Plaintiffs' proposal has several serious flaws. First, it ignores that Columbia's expected counterclaims for patent infringement share common issues with plaintiffs' allegations that the '275 patent is invalid and unenforceable. It is well established that the first step in any infringement analysis is claim construction. As plaintiffs concede, the same is true for their claims that the '275 patent is invalid and unenforceable. To avoid unnecessary duplicative activity after remand, it is important for claim construction in this case to take into account the interpretation of claims relevant to Columbia's infringement contentions as well as plaintiffs' invalidity and unenforceability contentions.

Second, plaintiffs' proposal ignores that Columbia's expected infringement counterclaims against various plaintiffs will themselves share common issues that would be more efficiently handled during consolidated pretrial proceedings. All of the infringement counterclaims will address the technology claimed in the '275 patent. Thus, Columbia's discovery requests to each plaintiff regarding infringement issues will have many similarities to one another. To the extent that there are disputes regarding the appropriate scope of such

discovery or other issues, it makes sense to handle them together in a single proceeding to avoid duplicative effort and inconsistent results. Moreover, many of the same witnesses can expect to be deposed with respect to plaintiffs' invalidity and unenforceability allegations and Columbia's expected infringement counterclaims—in particular, the named inventors on the '275 patent and the attorneys who prosecuted that patent before the Patent and Trademark Office. It would be unfair and inefficient to require these individuals (and possibly others, such as experts) to stand for deposition on multiple occasions—first, in these consolidated proceedings, and then, on multiple occasions, in each separate action after remand.

Third, plaintiffs' proposal would likely double the length of this litigation. Instead of conducting discovery on Columbia's infringement counterclaims concurrently with discovery on plaintiffs' invalidity and unenforceability claims, plaintiffs would have the parties start all over again in each individual case after remand—and without any of the benefits of coordinated pretrial proceedings. This is transparent attempt to make the cost of pursuing multiple infringement actions unduly—or prohibitively—expensive for Columbia, a non-profit educational institution. Significantly, Columbia's proposed schedule would add only *three additional months* for fact discovery, giving the parties approximately one year to conduct all necessary fact discovery on plaintiffs' claims and Columbia's counterclaims.

Fourth, plaintiffs' proposal would seriously undermine any ability to settle these actions. This is because plaintiffs would face no risk in these consolidated proceedings, given that only plaintiffs' claims would be addressed. Thus, plaintiffs' proposed schedule essentially creates a no-lose scenario for plaintiffs in this multidistrict litigation: If they prevail on their invalidity claims, they will have no further royalty obligations to Columbia. If Columbia prevails on their invalidity claims, plaintiffs are no worse off than they were before the actions began. Columbia

believes that it is unfair to insulate plaintiffs from any risk in these cases—and require Columbia to litigate its infringement counterclaims in separate proceedings without the benefits provided by the multidistrict litigation rules.

In short, plaintiffs’ proposal conflicts with one of the fundamental benefits of consolidation under 28 U.S.C. § 1407—a benefit recited in the text of the order granting Columbia’s MDL motion: “[W]e observe that transfer under Section 1407 has the benefit of placing all actions in this docket before a single judge who can structure pretrial proceedings to consider all parties’ legitimate needs while ensuring that common parties and witnesses are not involved in discovery demands and other pretrial matters in one action that duplicate activity that has already occurred or would occur in the other actions.” Transfer Order of April 8, 2004, at 2. It is for this reason that cases granting transfer under Section 1407 routinely recite the benefits of litigating common and non-common issues together. *See In re Ephedra Products Liability Litigation*, No. 1598, 2004 WL 835971 (J.P.M.L. Apr. 13, 2004) (the multidistrict transfer statute “has the salutary affect of placing all the related actions before a single judge who can formulate a pretrial program that...allows pretrial proceedings with respect to any non-common issues to proceed concurrently with pretrial proceedings on common issues”); *In re Zyprexa Products Liability Litigation*, No. 1596, 2004 WL 835880 (J.P.M.L. Apr. 14, 2004) (“Discovery [in multidistrict litigation] with respect to any case-specific issues can proceed concurrently with discovery on any common issues.”).

2. Merging Claim Construction and Summary Judgment: The second major structural difference relates to claim construction. Plaintiffs propose that the Court merge claim construction and summary judgment into a single proceeding, instead of having separate claim construction briefing and a separate *Markman* hearing. Plaintiffs propose to merge these two

proceedings in the context of a case schedule that addresses only their invalidity and unenforceability contentions. Plaintiffs' purpose in requesting a merger of claim construction and summary judgment is rather transparent: They want to be able to argue, at least implicitly, that the benefit of adopting *their* interpretation of the disputed claims is that '275 patent is invalid and no further proceedings are required.

Columbia believes that this multidistrict litigation should follow the common practice in which claim construction precedes any dispositive motions. *See, e.g., Control Resources, Inc. v. Delta Electronics, Inc.*, 133 F. Supp. 2d 121, 126 (D. Mass. 2001) ("As is the practice of this Court, a Markman hearing was conducted prior to and entirely independently of the summary judgment hearing"). While Columbia acknowledges that it may be appropriate to coordinate claim construction and dispositive motion scheduling in certain situations, the sheer volume of parties and issues in this multidistrict litigation counsels against such a schedule. Claim construction is relevant not only to plaintiffs' invalidity and unenforceability claims, but also to Columbia's expected counterclaims for infringement. It would be unduly burdensome and unfair to require Columbia to address multiple claim construction and summary judgment briefs simultaneously. Moreover, Columbia believes it is highly doubtful that plaintiffs' complex validity challenges can be resolved at the summary judgment stage, thus eliminating any perceived benefit of coordinating summary judgment and claim construction.

Plaintiffs also propose that the parties engage in nearly nine months of discovery before briefing claim construction. Extrinsic evidence is typically not a part of the claim-construction process. *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1583 (Fed. Cir. 1996) ("In most situations, an analysis of the intrinsic evidence alone will resolve any ambiguity in a claim term. In such circumstances, it is improper to rely on extrinsic evidence."). Columbia believes that the

parties and the Court would benefit from an early exchange of claim construction positions and the resolution of the parties' inevitable disputes at an early claim construction hearing. An early *Markman* hearing would serve to focus many of the key issues in the case that turn upon the interpretation of the '275 patent—in particular, plaintiffs' double-patenting allegations and Columbia's expected infringement counterclaims. Moreover, an early claim construction ruling would promote settlement discussions, for the ruling will no doubt fundamentally impact the merits of the allegations of all parties in these cases.

3. **Early Disclosure of Invalidity and Infringement Positions:** The third major structural difference is Columbia's proposal that, at the outset of the case schedule, plaintiffs serve preliminary invalidity contentions and Columbia serve preliminary infringement contentions. This proposal is adopted from Rule 3 of the Patent Local Rules of the Northern District of California, a set of rules designed specifically to expedite and streamline the litigation of patent disputes. The rules provide for the party having the burden of proof on the fundamental issues in a patent case—infringement and invalidity—to disclose in detail their contentions and the extrinsic evidence supporting those contentions. This requirement makes sense, for the Federal Rules of Civil Procedure allow for highly generalized notice pleading in patent cases that gives the responding party little clue as to the factual basis for the pleader's position. For example, although double patenting is the plaintiffs' central invalidity contention in this case, not one of their complaints identifies the particular claim of the earlier Columbia patents that allegedly invalidates a particular claim of the '275 patent.

Plaintiffs have said that they do not want to have preliminary invalidity contentions or preliminary infringement contentions because they are "one-sided," in that only the party having the burden of proof must make the required disclosure. But it is only fair to have the party with

the burden of proof disclose the basis for its position at an early stage of the litigation. It makes no sense to force Columbia to prove why its patent is “valid” or to force plaintiffs to prove why their products are “non-infringing” in a vacuum. Once the party which has the burden of proof has presented its initial contentions, that party can then use appropriate discovery tools to determine the responding party’s defenses. Early disclosure of preliminary contentions on the central issues in this case will thus facilitate efficient discovery and resolution of these litigations.

F. Prospects for Settlement

The prospects for settlement are difficult to assess at this stage of the litigation and are different for different parties. The parties will inform the court when they believe that they are in a position to engage in meaningful settlement discussions.

The parties are not aware of events or actions within the control of the Court that would contribute to achieving settlements in the remaining cases.

G. Other issues

1. Periodic status conferences

All parties request that the Court conduct status conferences in this multidistrict litigation every two months. The parties expect that a schedule of periodic status conferences, set in advance, will greatly improve the efficiency with which the parties can present any disputes to the Court so that the progress of the coordinated actions will not be impeded.

2. Tutorial

The parties believe that a technology tutorial may aid the Court in conjunction with the *Markman* hearing. The parties are prepared to conduct such tutorial at the time of the *Markman*

hearing, or at such earlier date that is convenient for the Court. The parties request that the Court include such a tutorial in its scheduling order.

3. Discovery coordination and limitations

The parties have submitted various proposals concerning discovery coordination and limitations. These are attached at Tab 2.

4. Depositions and discovery materials from other cases

Plaintiffs are aware of two prior cases, *Biogen v. Berlex* and *Trustees of Columbia University in the City of New York v. Roche*, in which they believe discovery relevant to the issues in this multidistrict litigation has been taken.

In *Biogen v. Berlex*, Saul Silverstein, one of the inventors of the '275 patent, and Lawrence Chasin, a witness disclosed by Columbia in connection with the *Genentech* case, served as expert witnesses. Both testified about their work at Columbia at the time of the filing of the original parent application to the '275 patent. Under the terms of the applicable protective order, Biogen's counsel in the *Berlex* action cannot release these deposition transcripts even to Foley Hoag, counsel for Biogen in this proceeding, without the consent of Drs. Silverstein and Chasin, who are Columbia employees.

In *Columbia v. Roche*, an action to enforce the earlier patents in the family of the '275 patent, all three named inventors on the '275 patent and several other witnesses who plaintiffs believe have very important roles in this case were deposed concerning the alleged invention or inventions claimed in Columbia's earlier patents (Nos. 4,399,216, 4,634,665, and 5,179,017) and the prosecution of the applications leading up to those patents. Because these deposition transcripts are subject to a protective order in the *Roche* litigation, Plaintiffs believe counsel in

the pending cases cannot gain access to those transcripts unless those witnesses give consent.

Plaintiffs believe these witnesses are all controlled by Columbia.

In a letter dated March 22, 2004, counsel for plaintiffs requested the necessary consents from Columbia. Notwithstanding a follow-up letter dated April 22 and a request by telephone for a reply to these communications, Columbia has not responded. Plaintiffs request the Court's assistance in facilitating the exchange of these transcripts, since they may very significantly streamline the taking of the same witnesses' depositions in this case. Plaintiffs believe that obtaining access to these depositions may assist the parties in achieving agreement as to the number and length of depositions.

Columbia's position is that, once a discovery schedule and protective order have been entered in these actions, it will cooperate in the production of those portions of the above material that are discoverable.

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Respectfully submitted,

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